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**COLLAGEN SYNTHESIS IN AN ePTFE POLYMER IMPLANTED IN RABBIT CORNEA \*****DRUBAIX I<sup>1,2</sup>, LEGEAIS JM<sup>1,3</sup>, SAVOLDELLI M<sup>1</sup>, MENASCHE M<sup>1</sup>, ROBERT L<sup>2</sup>, RENARD G<sup>1,3</sup>, POULIQUEN Y<sup>1,3</sup>.**

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**Purpose:** Our previous studies demonstrated functional differentiated cells and collagen synthesis in the pores of an ePTFE implant. This study quantifies and identifies collagen types synthesized in this polymer.

**Methods:** Rabbit eyes were implanted with a 6mm diameter disc of an ePTFE disc (Impra®) (0.2mm thick, 50µm pore size with a mean porosity of 88±4% and the channels were perpendicular to the surface). Collagens pepsin-extracted from the polymer and implanted rabbit cornea and from control corneal stroma were quantified using OH-Proline. Semi-quantitative analysis of collagen types was performed using densitometry after SDS-PAGE.

**Results:** In the polymer, three months after the implantation, the collagen to total protein ratio reached 0.70, similar to control corneal stroma. Moreover, from the third month following implantation in both implant and implanted stroma, total protein and collagen densities were similar to those observed in control. The collagen synthesized in the polymer was mainly type I (87%) plus a small amount of type III (8%) one month after the implantation. From the third month after implantation the collagen distribution was similar to that of the control cornea and remained constant thereafter in the polymer and in the implanted stroma.

**Conclusion** Keratocytes invaded the polymer, rapidly adopted a corneal phenotype distinct from dermal or scarring phenotype as revealed by the collagen types produced in this implant. Moreover, our results confirm that this polymer offers a good interface perfectly compatible with the native cornea.

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**A NOVEL BIOINTEGRABLE ARTIFICIAL CORNEA****LEGEAIS JM.<sup>1</sup> RENARD G.<sup>1</sup> and POULIQUEN Y.<sup>1</sup>**<sup>1</sup> Département d'Ophthalmologie, INSERM U 86, Hôtel-Dieu de Paris (France)

**Purpose :** We present a new generation of biointegrable artificial corneas using both hydrophilic transparent polytetrafluoroethylene for the flange and a new soft copolymer structure for the optical system.

**Materials :** The expanded polytetrafluoroethylene we used for the flange was 200 microns thick with 50 microns pore diameters. To modified the hydrophilic property of the polymer we induced photochemical modification on the fluororesin surface by cold plasma treatment or by using amphotheric molecules as lipoprotein. The optical system is composed of a copolymer with medical grade silicone coated with polyvinylpyrrolidone (PVP). The optical system is 7 mm of diameter with a 500 microns thick and was devised using a mathematical model using finite element technic. The junction between the flange and the optic is produced by interpenetration of both polymers.

**Results :** We were able to accurately measure intraocular pressure with a Goldmann tonometer in an artificial chamber. After photochemical modification we did not observed important modification of hydrophilic property. In contrary, after lipoprotein coating the modified PTFE remained hydrophilic and transparent after 6 months in BSS. We evaluated the biocompatibility of our hydrophilic PTFE and preliminary implantations in rabbits of the novel corneal prosthesis was performed, we did not observed adverse reaction. Histological results shows that biointegration of the modified flange was observed in the first 15 days and was optimal in the first month. The surface modification with lipoprotein increase the colonization of 2.0 to 3 fold.

**Conclusions :** Future in vivo evaluation must be performed before to claim the safety of the novel artificial corneal prosthesis.

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**TITLE: BIOLOGICAL CORNEAL EXCHANGE - AN ALTERNATIVE TO PENETRATING KERATOPLASTY AND KERATOPROSTHESIS?****ROHRBACH J.M., WOHLRAB TH.-M. and SADOWSKI B.**

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**Background:** In cases of bilateral severe burns, ocular pemphigoid or Stevens-Johnson-Syndrome, biological materials could possibly combine the advantages of penetrating keratoplasty (missing artificial implant-tissue-interaction) and keratoprosthesis (reduced, but more permanent transparency). Based on theoretical grounds and practical experience, hyaline cartilage seems the best candidate for a biological corneal exchange material.

**Material and methods:** Slices of hyaline cartilage from the bovine sternum were prepared at a thickness of ca. 300 µm with a diameter of 6 mm. These slices were implanted into 4 rabbit eyes instead of the natural cornea. After 8 to 29 days, the eyes were enucleated and investigated morphologically.

**Results:** The cartilage allowed visualization of the iris and to a certain extent of retinal vessels. The slices were partially or nearly totally covered by epithelial cells. Perforation, however, occurred in 3 eyes. There was almost no inflammatory reaction around the cartilage. It was bound to the cornea by fibroblastic proliferations. Vascularization of the cartilage was not observed. With the exception of anterior synechiae, there were no secondary intraocular changes.

**Conclusions:** As prognosis of penetrating keratoplasty is very bad in certain instances, and as keratoprosthesis bears several complications as well, the search for alternatives seems desirable. Though the results are preliminary, and several problems have still to be overcome, there is some evidence that hyaline cartilage could serve for biological corneal exchange.

**BIOINTEGRABLE KERATOPROSTHESIS, 4 YEARS STUDY****LEGEAIS JM.<sup>1</sup> RENARD G.<sup>1</sup> and POULIQUEN Y.<sup>1</sup>**<sup>1</sup> Département d'Ophthalmologie, INSERM U 86, Hôtel-Dieu de Paris (France)

**Purpose :** We present a prospective clinical human study of a biocolonizable keratoprosthesis on 41 eyes of 41 patients.

**Methods :** To promote implant stability, the 9 mm diameter haptic was fashioned using a custom-made microporous fluorocarbon with a 5 mm diameter, 2.67 mm long, central optic made of medical grade polymethylmetacrylate (PMMA-CQ), giving a global visual field of 110° to 130°. Only bilateral blind patients with untreatable corneal diseases were included in the study. The haptic was inserted into a lamellar pocket delaminated in the stroma and the optic positioned through a hole trephined in the central cornea.

**Results :** The average follow-up was 26 months (range 3 to 46 months). The host corneal fibroblasts penetrated and proliferated into the peripheral microporous fluorocarbon and provided anchorage between cornea and prosthesis. Twenty two patients (53 %) had visual acuity improvements. Mean corrected final visual acuity was 20/200 (range 20/30 to 20/400). Eleven anatomic failures occurred (6 extrusions, 3 dislocation of the optic, and 2 endophthalmitis). We had one case of treatable glaucoma and two cases of retinal detachment. We successfully removed 6 out of 11 retroprosthetic membranes that had occurred.

**Conclusions :** The biocompatible inert microporous polymer did not eliminate all mechanical complications associated with keratoprosthesis.

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